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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,184	11/21/2003	Yong-Jin Wu	CT-2755-NP	3234

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EXAMINER	
SACKEY, EBENEZER O	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,184	WU ET AL.	
	Examiner	Art Unit	
	EBENEZER SACKEY	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 1-3 is/are allowed.

6)☒ Claim(s) 4-6 is/are rejected.

7)☒ Claim(s) 7 and 8 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 02/05/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-8 are pending.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed 02/05/04 is acknowledged and has been entered into the file. A signed copy of the 1449 is attached herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for migraine, pain, as recited in claims 7 and 8, epilepsy and convulsions, does not reasonably provide enablement for the remaining disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 5 lacks practical utility except one of ordinary skill in the art reads the specification into the claim, which is contrary to the office practice or to several precedent court rulings. This is an attempt by applicants to claim treatment of diseases, which may be discovered in the future arising from opening of KCNQ potassium channels. This is a reach through claim.

The notion that the various disorders enumerated can be treated by one compound has not been substantiated by the current state of the art literature. See Gribkoff "The therapeutic potential of neuronal KCNQ channel modulators", discloses compounds such as retigabine, N-(2-amino-4-(4-fluorobenzylamino)phenyl)carbamic acid ethyl ester, a known KCNQ 2 or 3 opener, having undergone more testing than instant compounds in clinical trials for uses listed above. Please note page 742, column 2, lines 1-46 where KCNQ modulation as treatment for pain is discussed. Also note the limited effect of KCNQ modulation in relation to other disorders "----at present there are almost no data to specifically support any other indications." Hence, in the absence of animal studies and correlation between the *in vitro* studies for the rest of the

diseases covered, there is no sufficient evidence or facts to support all the claimed uses. Note the ruling in *Hoffman v. Klaus,* 9 USPQ 2d. 1657 and also *Ex parte Powers*, 220 USPQ 924. Therefore, given the level of skill in the pharmaceutical art, which is low and lack of direction (i.e., art recognized tests) as well as working examples employing such tests, this rejection applies.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 5 and 6 are of indeterminate scope. Defining a disease(s) by its (their) underlying cause renders the scope of intended uses indeterminate since the claim language may read on diseases not yet understood. Additionally, determining whether a given disease responds or not to "activation" of KCNQ potassium channels in a mammal involves much experimentation since a negative response from one patient does not mean the drug isn't useful as no drug has 100% effectiveness. Thus, what "success rate" determines if a particular drug is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, second paragraph is whether applicants have clearly defined "their" invention

not what may be discovered by feature research as this type of claim language clearly requires. Furthermore, how does one determine who is in need of such treatment? The specification fails to provide guidance as to what cutoff point determines the need for activation of KCNQ potassium channel for even one mammal much less all mammals being claimed.

Claims 1-3 are allowed over the prior art of record. A search in the relevant art area did not yield any relevant art closely related to compounds or compositions containing compounds of structural formula (I).

Allowable Subject Matter

Claims 7 and 8 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS
January 9, 2006

T. Solola
Primary Patent Examiner
Art Unit 1626, Group 1600
Technology Center 1